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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/121,300

07/23/1998

BRUCE G. KANIA

3295-0024-0C

3160

8698

7590

08/24/2006

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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/121,300

Applicant(s)

KANIA ET AL.

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-78, 80, 85, 88, 89, 92-94, 96, 99, 102, 103, 106, 107, 110, 111, 114, 115, 118-121, 124-165 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4-26-06 (2 pages)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 75-78,80,85,88,89,92-94,96,99,102,103,106,107,110,111,114,115,118-121 and 124-165.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75, 78, 80, 85, 106, 107, 114, 115, 134, 135, 138, 152, 153, and 156 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Silipos Silosheath #12155. (According to the Information Disclosure Statement of June 4, 2004, Silosheath #12155 corresponds to item no. 1215 on the Silipos invoice dated November 1, 1993.) The model submitted is clearly of a fabric coated seamlessly on only an inside surface with a polymeric cushioning material, and the accompanying brochure states that said material is a patented gel formulated with medical grade mineral oil. Given an appropriately sized and shaped amputation stump, the gel substantially (MPEP § 2173.05(b)) conforms to the shape of said stump when the liner is worn.

Claims 88, 89, 126, 127, 136, 137, 139, 140, 154, 155, 157, and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silipos Silosheath #12155. Regarding claims 88, 89, and others, biocides and vitamins were well known in the art at the time of the present invention and would have been obvious in order to prevent infection and promote healing. Regarding claim 126 and others, docking means molded to liners were likewise common in the art and would have been obvious in order to affix the Silosheath to the stump socket.

Claims 76, 77, 80, 92-94, 96, 99, 102, 103, 107, 110, 111, 115, 118-121, 124, 125, 128-133, 141-151, and 159-165 rejected under 35 U.S.C. 103(a) as being unpatentable over Silipos Silosheath #12155, in view of Mushenko et al., SU 1739990 A1. Regarding claim 76 and others, cushioning material thickened at distal portions and thinner at posterior upper and middle portions is taught by Mushenko et al. (English translation of Mushenko et al.: page 5, lines 14-16; page 6, lines 5-9) and would have been obvious for the Silipos Silosheath in order to customize the fit for a particular amputee and to reduce trauma to skin at local bony prominences (*ibidem*: page 3, line 1), with further motivation being provided by both references being directed to “improving the performance of cushions” (*ibidem*: page 3, lines 1-2).

The copy of the Declaration under 37 CFR 1.132 filed in said parent application has been reviewed, but it does not address the current grounds of rejection relative to the scope of the present claims.

The Applicant's remarks have been considered. The Applicant makes reference to certain documents in parent application serial no. 08/611,306, but these documents inherently refer to Silipos Silosheath item #1240, of record in said parent application, whereas the present rejection is based upon Silipos Silosheath item #12155 (which corresponds to item #1215, as explained above and in the previous Office action). The examiner possesses one of each item (as a result of the Information Disclosure Statement filed on November 6, 2000), and item #12155 (unlike item #1240) clearly has a gel coating on only one side. The Applicant argues that “a Silosheath® is not a cushion liner” (page 14, lines 20-21, of the Applicant's reply of June 8, 2006), but inspection of item #12155 shows that the gel material is sufficiently thick to serve as a cushion, particularly near the distal end.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**